PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Kineret (anakinra)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>Must use valid NDC code</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Home</td>
</tr>
<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel &amp; Humira for RA</td>
</tr>
<tr>
<td>QUANTITY LIMIT</td>
<td>28 syringes per 28 days</td>
</tr>
<tr>
<td>LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY</td>
<td>Click Here</td>
</tr>
</tbody>
</table>

Kineret (anakinra) is a non-preferred product and will only be considered for coverage under the pharmacy benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

**CRYOPYRIN-ASSOCIATED PERIODIC SYNDROME (CAPS)**

For **initial** authorization:
1. Member must be diagnosed with Neonatal-Onset Multisystem Inflammatory Disease (NOMID); AND
2. Prescriber has submitted laboratory evidence of a genetic mutation in the Cold-Induced Auto-Inflammatory Syndrome 1 (CIAS1—sometimes referred to as the NLRP3); AND
3. Medication must be prescribed by a rheumatologist or under recommendation of a rheumatologist or CAPS specialist; AND
4. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy.
5. **Dosage allowed:** Initial dose: Inject 1-2 mg/kg subcutaneously once daily in 1 or 2 divided doses; adjust dose in 0.5-1 mg/kg increments as needed. Usual maintenance dose: 3-4 mg/kg once daily (maximum of 8 mg/kg per day).

*If member meets all the requirements listed above, the medication will be approved for 12 months.*

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

*If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*
For **initial** authorization:
1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with at least **two** non-biologic DMARDs (i.e. methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDs. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND
5. Member must have tried and failed treatment with both Enbrel and Humira.
6. **Dosage allowed:** Inject 100 mg subcutaneously once daily.

**If member meets all the requirements listed above, the medication will be approved for 12 months.**

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

**If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.**

CareSource considers Kineret (anakinra) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Ankylosing Spondylitis
- Anterior cruciate ligament injury
- Diabetes mellitus (type 1 and type 2)
- Familial Mediterranean fever
- Fatigue associated with Sjogren’s syndrome
- Gout
- Heart failure (prevention of heart failure after acute MI)
- Inflammatory bowel disease
- Kawasaki disease
- Lupus arthritis
- Myopathy/myositis
- Non-neuropathic hereditary familial amyloidosis
- Osteoarthritis
- Pyoderma gangraenosum
- Reactive arthritis
- Systemic lupus erythematosus

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/10/2017</td>
<td>New policy for Kineret created. Policy SRx-0042 archived. List of diagnoses considered not medically necessary was added.</td>
</tr>
</tbody>
</table>
References:


Effective date: 05/10/2017
Revised date: 05/10/2017